# VIDAS® Free PSA rt (FPSA)

IVD

**Caution:** The concentration of free PSA in a given specimen determined with different assays can vary due to the differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the assay used. Free and total PSA values should be obtained using assays from the same manufacturer

**INTENDED USE:** VIDAS® Free PSA rt is an automated quantitative test for use on the VIDAS instruments, for the quantitative measurement of the free fraction of prostate specific antigen (PSA) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS Free PSA rt is intended to be used in conjunction with the VIDAS TPSA assay in men age 50 years or older who have digital rectal examination (DRE) that is not suspicious for prostate cancer and VIDAS TPSA values between 4 and 10 ng/mL to determine the % Free PSA value. The VIDAS % Free PSA value can be used as an aid in discriminating between prostate cancer and benign disease. Prostate biopsy is required for diagnosis of prostate cancer.

## SUMMARY AND EXPLANATION

Prostate-specific antigen (PSA) is a glycoprotein which belongs to the kallikrein family. PSA has a molecular weight of 30,000 Daltons (1). PSA is principally produced by the glandular epithelium of the prostate, and is secreted in the seminal fluid. PSA is also present in urine and blood. PSA acts on seminal fluid to fluidify and increase sperm mobility.
PSA is present in blood in three main forms (2, 3). The most important immunoreactive form is PSA bound to Alpha-1-antichymotrypsin (PSA-ACT). Free PSA is the other immunoreactive form present in serum. The third main form of PSA, bound to alpha-2-macroglobulin, cannot be detected by enzyme immunoassay tests.
PSA levels rise in prostatic pathologies such as benign prostatic hyperplasia (BPH) or prostate cancer (4). Testing for PSA and its evolution is useful for monitoring and controlling the efficacy of prostatic carcinoma therapy.
The percentage of free PSA in serum is described as being significantly higher in patients with BPH than in patients with prostate cancer (5). Calculation of the percentage of free PSA, determined by dividing the free PSA (FPSA) concentration by that of total PSA (TPSA), has been suggested as a way of improving the differentiation of BPH and prostate cancer (2).
The VIDAS Free PSA rt assay is used to measure the free PSA concentration in order to calculate the free PSA percentage.

## PRINCIPLE

The assay principle combines a two step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).
The Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.
All of the assay steps are performed automatically by the instrument. The sample is cycled in and out of the SPR several times. This operation enables the monoclonal antibody fixed onto the interior wall of the SPR to capture the free fraction of the prostate specific antigen present in the sample. Unbound components are eliminated during the washing steps. The alkaline phosphatase labeled monoclonal antibody is then incubated in the SPR where it binds with the prostate specific antigen. Unbound conjugate is then eliminated during the washing steps.
During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of prostate specific antigen free fraction present in the sample.
At the end of the assay, results are automatically calculated by the VIDAS instrument in relation to the calibration curve stored in memory, and then printed out.

**CONTENT OF THE KIT (30 TESTS) – RECONSTITUTION OF REAGENTS:**

| | | |
|---|---|---|
| 30 FPSA strips | STR | Ready-to-use. |
| 30 FPSA SPRs<br>1 x 30 | SPR | Ready-to-use.<br>Interior of SPRs coated with mouse monoclonal anti-free PSA specific immunoglobulins. |
| FPSA control<br>1 x 2 mL (lyophilized) | .C1 | Reconstitute with 2 mL of distilled water. Let stand for 30 minutes, then mix.<br>Stable after reconstitution for 24 hours at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible.<br>Human serum* + human PSA (free fraction) + preservatives.<br>The confidence interval in ng/mL is indicated on the MLE card after the following mention : "Control C1 Dose Value Range". |
| FPSA calibrator<br>1 x 2.5 mL | S1 | Ready-to-use.<br>Bovine albumin + human PSA (free fraction) + 0.9 g/L sodium azide.<br>The concentration in ng/mL is indicated on the MLE card after the following mention : "Calibrator (S1) Dose Value". The confidence interval in "Relative Fluorescence Value" is indicated on the MLE card after the following mention : "Calibrator (S1) RFV Range". |
| 1 MLE card | | Specifications sheet containing the factory master calibration data required to calibrate the test. |
| 1 Package insert | | |

**The SPR®**

The interior of the SPR is coated during production with mouse monoclonal immunoglobulins directed against the free fraction of the prostate specific antigen. Each SPR is identified by the code "FPSA". Only remove the required number of SPRs from the pouch and **reseal the pouch correctly after opening.**

**The strip**

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

**Description of the FPSA strip:**

| Wells | Reagents |
|---|---|
| 1 | Sample well. |
| 2 - 3 - 4 | Empty wells. |
| 5 | Conjugate: alkaline phosphatase labeled monoclonal anti-PSA immunoglobulins (mouse) + Tris (0.1 mol/L, pH 6.5) + NaCl (0.1 mol/L) + calf serum (5%) + 0.9 g/L sodium azide (400 µL). |
| 6 - 7 - 9 | Wash buffer: Tris (0.05 mol/L, pH 7.4) + NaCl (0.4 mol/L) + Tween (0.05%) + 1 g/L sodium azide (600 µL). |
| 8 | Diluent: Tris (0.1 mol/L, pH 7.0) + NaCl (0.1 mol/L) + calf serum (5%) + sodium azide 0.9 g/L (400 µL). |
| 10 | Cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + diethanolamine (DEA*) (0.62 mol/L or 6.6%, pH 9.2) + 1 g/L sodium azide (300 µL). |

*** IRRITANT reagent:**

- **R 36 :** Irritating to eyes.
- **S 26 :** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

For further information, refer to the Safety Data Sheet available on request.

**MATERIAL REQUIRED BUT NOT PROVIDED**

- Pipette with disposable tip calibrated to dispense 200 µL.
- Powderless, disposable latex gloves.

**WARNINGS AND PRECAUTIONS**

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).**
- This product has been tested and shown to be negative for HBs antigen, antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Do not use the SPRs if the pouch is pierced.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents (or disposables) from different lots.
- Use **powderless** gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The substrate in well 10 contains an irritant agent (6.6% diethanolamine). Refer to the risk phrase "R" and the precautions "S" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5% sodium hypochlorite. See the Operator's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The VIDAS® and mini VIDAS instruments should be regularly cleaned and decontaminated (see the Operator's Manual).

## STORAGE CONDITIONS

- Store the VIDAS® Free PSA rt kit at 2-8°C.
- **Do not freeze SPRs, strips or calibrator.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label. Refer to the kit composition table for special storage conditions.

## SPECIMENS

### Specimen type

Serum

### Sample preparation

Follow the tube manufacturer's recommendations for use.

Serum collection tubes with no additive : wait for samples to coagulate and **centrifuge** to eliminate fibrin.

**Note:** blood sampling tube results may vary from one manufacturer to another depending on the materials and additives used.
It is the responsibility of each laboratory to validate the type of sample tube used and to follow the manufacturer's recommendations for use.

### Specimen stability:

Serum samples can be stored at 2-8°C for up to 24 hours or at -25 ± 6°C for up to 2 months, from collection to assaying. For better storage, avoid successive freezing and thawing. Some publications indicate that certain samples may lose their immunoreactivity during storage (6).

### Sample-related interference

None of the following factors have been found to significantly influence this assay.
- hemolysis (after spiking samples with hemoglobin up to a concentration of 12 mg/mL),
- lipemia (after spiking samples with lipids/triglycerides up to a concentration of 30 mg/mL),
- bilirubinemia (after spiking samples with unconjugated bilirubin at a concentration of 0.60 mg/mL).

However, it is recommended not to use samples that are clearly hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

## INSTRUCTIONS FOR USE

**For complete instructions, see the VIDAS® or mini VIDAS Operator's Manual.**

### VIDAS® PTC protocol data entry

When using the assay for the first time, **and before reading the MLE card**, scan the bar code(s) (at the end of the package insert) using the VIDAS or mini VIDAS bar code reader. This reading will allow VIDAS PTC protocol data to be transferred to the VIDAS PC and/or mini VIDAS instrument software for its update. These data should only be read the first time the assay is used.

### Master lot data entry

**Note: When using the assay for the first time, it is imperative to enter the VIDAS® PTC protocol data (bar codes at the end of the package insert) before reading the MLE card. If the MLE card has been read before the VIDAS PTC protocol data, read the MLE card again.**
Before each new lot of reagents is used, specifications (or factory master calibration curve data) must be entered into the instrument (VIDAS or mini VIDAS) using the master lot entry (MLE) card (specifications sheet) included in each kit. If this operation is not performed **before initiating the tests**, the instrument will not be able to print results. The master lot data need only be entered once for each lot.
It is possible to enter data automatically using the MLE card or manually.

### Calibration

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrator, identified by S1, must be tested in **duplicate** (see Operator's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.
VIDAS Free PSA rt has been calibrated to the First International Standard for free Prostate-specific antigen (7). Depending on the dilution mode and the type of diluent used with the International Standard, a bias of up to 25% may be observed.

### Procedure

1. **Only remove the required reagents from the refrigerator and allow them to come to room temperature for at least 30 minutes.**
2. Use one "FPSA" strip and one "FPSA" SPR® for each sample, control or calibrator to be tested. **Make sure the storage pouch has been resealed after the required SPRs have been removed.**
3. Type or select "FPSA" to enter the test code. The calibrator must be identified by "S1", and tested in **duplicate**. If the control is to be tested, it should be identified by "C1".
4. Mix the calibrator, control and samples using a Vortex-type mixer
5. Pipette **200 µL** of calibrator, sample or control into the sample well.
6. Insert the SPRs and strips into the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
7. Initiate the assay as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument. The assay will be completed within approximately 60 minutes.
8. After the assay is completed, remove the SPRs and strips from the instrument.
9. Dispose of the used SPRs and strips into an appropriate recipient.

## RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested. The first reading is a background reading of the substrate cuvette before the SPR is introduced into the substrate. The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR. The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.
The results are automatically calculated by the instrument using calibration curves stored by the instrument (mathematical model: 4 parameter logistics model). The concentrations are expressed in ng/mL.

Samples with free PSA concentrations greater than 10 ng/mL should be retested after being diluted in the **VIDAS® TPSA kit diluent (ref. 30 428-01)**. If the dilution factor has not been entered when the Work List was created (see Operator's Manual), multiply the result by the dilution factor to obtain the sample concentration.

To calculate the free PSA percentage, determine for the same sample the Total PSA concentration using VIDAS TPSA (ref. 30428-01) and the free PSA concentration using VIDAS Free PSA rt (ref. 30457).

Calculate the percentage as follows:

$$\frac{\text{FPSA concentration}}{\text{TPSA concentration}} \times 100$$

Interpretation of test results should be made taking into consideration the patient's history, and the results of any other tests performed. Serum FPSA concentrations, regardless of the value should not be interpreted as definitive evidence for the presence or absence of prostate cancer. The results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. Prostate biopsy is required for the diagnosis of cancer.

## QUALITY CONTROL

A control is included in each VIDAS Free PSA rt kit. This control must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using this control.
Results cannot be validated if the control value deviates from the expected values.

### Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

## LIMITATIONS OF THE METHOD

- Interference may be encountered with certain sera containing antibodies (e.g. human anti-mouse antibodies (HAMA) or heterophilic antibodies) directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history, and any other tests performed.
- The free PSA percentage can only be interpreted taking into consideration clinical data and information available from other diagnostic procedures.
- Free PSA assays should not be performed on patients who have received a contrast medium within the previous 24 hours (8).

## RANGE OF EXPECTED VALUES

A multicenter study was performed using samples from 2179 males ages ≥ 50 years collected in 36 sites across the United States.
In this study, 95% of the specimens from 216 apparently healthy males (regardless of their VIDAS TPSA value) had free PSA values of ≤ 0.86 ng/mL.
The disease cohort includes 679 males referred to an urologist for evaluation of possible prostate cancer. Inclusion criteria include VIDAS TPSA values between 4-10 ng/mL and DRE results not suspicious for Prostate cancer (median age was 64.0 years). All patients underwent a transrectal prostate biopsy and diagnosis of prostate cancer or benign prostate disease (BPH) was based on pathological examination of a minimum of 6 core biopsies from each subject (62% of all biopsies were 12 cores). Of these 679 males, 8.7% were African American, 1% were Asian, 81.2% were Caucasian, 8% were Hispanic and 1% were other racial groups.
Free PSA values were determined using the VIDAS Free PSA rt assay and the %FPSA was calculated for each individual with VIDAS TPSA values between 4 and 10 ng/mL.

The distribution of % FPSA values by biopsy outcomes is shown below:

| Biopsy results | Number of subjects | %FPSA ranges | | | |
|---|---|---|---|---|---|
| | | <=10 | >10 - <20 | >=20 - <25 | >=25 |
| Benign | 437 | 33 | 233 | 85 | 86 |
| Malignant | 242 | 66 | 133 | 26 | 17 |

The % FPSA result may be used in evaluating the need for prostate biopsy either by considering:
1) the relative risk of prostate cancer in individual men or 2) by managing patients using a single cut-off approach.

**1- Individual risk assessment**

The probability of finding prostate cancer with TPSA between 4-10 ng/mL increases with increasing age and with decreasing % FPSA. Results are reported below:

| Probability of finding Prostate cancer on core biopsy by age (95% CI) | | | |
|---|---|---|---|
| % FPSA | 50 – 59 years | 60 – 69 years | >=70 years |
| <=10 | 53.8% (37.2 – 69.9%) (21/39) | 76.9% (60.7 – 88.9%) (30/39) | 71.4% (47.8 – 88.7%) (15/21) |
| >10 - <20 | 28.3% (20.7 – 37.0%) (36/127) | 35.3% (28.1 – 43.1%) (59/167) | 52.8% (40.7 – 64.7%) (38/72) |
| >=20 - <25 | 12.5% (2.7 – 32.4%) (3/24) | 25.9% (15.3 – 39.0%) (15/58) | 27.6% (12.7 – 47.2%) (8/29) |
| >= 25 | < 1% (0 – 36.9%) (0/8) | 13.0% (4.9 – 26.3%) (6/46) | 22.4% (11.8 – 36.6%) (11/49) |

**2- Single cut-off**

Alternatively, a single cut-off may be used for males in all age groups. Sensitivities (% of prostate cancer detected) and specificities (% of biopsies avoided in males without prostate cancer) can be calculated for various % FPSA cut-offs.

| | Malignant biopsies | Benign biopsies |
|---|---|---|
| % FPSA cut-off | Sensitivity (95% CI) | Specificity (95% CI) |
| 23 | 90.5% (86.1 – 93.9%) (219/242) | 26.5% (22.5 – 30.9%) (116/437) |
| 26 | 93.4% (89.5 – 96.2%) (226/242) | 16.7% (13.3 – 20.5%) (73/437) |
| 29 | 94.6% (91.0 – 97.1%) (229/242) | 10.8% (8.0 – 14.0%) (47/437) |
| 53 | 99.2% (97.0 – 99.9%) (240/242) | 0% (0.0 – 0.8%) (0/437) |

A cut-off of 23% results in the detection of 90.5% of prostate cancers and avoids unnecessary biopsy in 26.5% of men without prostate cancer.

It is recommended that each laboratory establishes its own reference values using a rigorously selected population.

## PERFORMANCE

Studies performed using VIDAS® Free PSA rt gave the following results:

**Measurement range**

The measurement range of the VIDAS Free PSA rt assay is: 0.05 - 10 ng/mL.

**Detection limits**

Based on CLSI® document EP17-A, detection limit results are estimated to be less than **0.05 ng/mL**.

**Hook effect**

No hook effect was found in PSA free fraction concentrations up to **381,000 ng/mL.**

**Precision**

Three serum samples were tested in quadruplicate in 20 different runs (2 runs per day over 10 days) with 2 reagent lots using a single instrument at each of three sites (N = 480).

The repeatability (intra-run precision), inter-run precision, inter-day precision, and total precision (intra-run, inter-run, inter-day) were calculated according to the CLSI EP5-A2 document:

| Site | Source | Pool A (0.52 ng/mL) | | Pool B (1.92 ng/mL) | | Pool C (4.97ng/mL) | |
|---|---|---|---|---|---|---|---|
| | | Lot 1 (CV%) | Lot 2 (CV%) | Lot 1 (CV%) | Lot 2 (CV%) | Lot 1 (CV%) | Lot 2 (CV%) |
| 1 | Day-to-day | 1.9 | 1.2 | 0.7 | 1.3 | 0 | 0.7 |
| | Run-to-run | 2.7 | 0 | 2.0 | 0 | 1.3 | 0 |
| | Intra-Assay | 3.8 | 2.8 | 2.5 | 2.6 | 3.0 | 2.5 |
| | Total | 5.0 | 3.1 | 3.3 | 3.0 | 3.3 | 2.6 |
| 2 | Day-to-day | 1.4 | 1.7 | 0 | 1.8 | 0.3 | 1.4 |
| | Run-to-run | 2.2 | 1.1 | 2.5 | 0.8 | 1.7 | 1.0 |
| | Intra-Assay | 4.5 | 3.0 | 2.9 | 2.6 | 3.2 | 2.4 |
| | Total | 5.2 | 3.6 | 3.9 | 3.3 | 3.6 | 3.0 |
| 3 | Day-to-day | 1.7 | 3.7 | 0.7 | 4.3 | 0.9 | 3.4 |
| | Run-to-run | 1.8 | 1.6 | 1.8 | 1.3 | 1.6 | 1.4 |
| | Intra-Assay | 2.3 | 2.8 | 3.7 | 2.3 | 2.5 | 3.2 |
| | Total | 3.4 | 4.9 | 4.2 | 5.0 | 3.1 | 4.9 |

**Analytical specificity**

No cross-reactivity was observed with CEA, PAP, AFP, CA 15-3, CA 125, or PSA-ACT.

**Interference and Cross-reactivity**

The following interferent and cross-reacting materials were tested by adding the identified substances in known concentrations to serum pools containing Free Prostate Specific Antigen (FPSA) at a mean concentrations of approximately 0.5 ng/mL and 5.0 ng/mL per CLSI® EP7-A document. The compounds showed no significant interference with the VIDAS® Free PSA rt assay at the specific levels indicated.

| Type Material | Material Tested | Tested Concentration | Material Tested | Tested Concentration | Material Tested | Tested Concentration |
|---|---|---|---|---|---|---|
| **Endogenous** | HAMA | 0.11 µg/mL | Rheumatoid Factor | 183 U/mL | Human Albumin | 120 mg/mL |
| | Transferrin | 5.0 mg/mL | Urea | 5.0 mg/mL | | |
| **Exogeneous** | Acetominophen | 25 µg/mL | Digoxin | 50 ng/mL | Phenytoin/ Dilantin | 0.1 mg/mL |
| | Acetylsalycilic acid/ Aspirin | 0.6 mg/mL | Gentamycin | 0.12 mg/mL | Propranol/ Inderal | 5.0 µg/mL |
| | Amikacin | 15 µg/mL | Heparin | 3.0 U/mL | Salicylate/ Salicylic Acid | 0.5 mg/mL |
| | Cortisol/ hydrocortisone | 1.0 mg/mL | Lithium Carbonate | 0.12 mg/mL | Theophylline/ Aminophylline | 40 µg/mL |
| | Coumarin | 1.4 mg/mL | Mitomycin C | 60 µg/mL | Caffeine | 0.1 mg/mL |
| | Cyclosporin A | 3.0 ng/mL | Paclitaxel | 4.0 ng/mL | | |
| **Anticancer Drugs** | 5'-Fluoruracil/ Adrucil | 1.0 mg/mL | Cisplatin dichloride | 0.1 mg/mL | Levamisole/ Tetramisole | 5.0 mg/mL |
| | Adriamycin/ Doxorubincin HCL | 0.1 mg/mL | Cyclophosphamide/ Cytoxan | 0.25 mg/mL | Novatrone/ Mitoxanntrone | 0.5 mg/mL |
| | Amethopterin/ Methotrexate | 1.0 mg/mL | Leucovin/ Folic Acid | 1.1 mg/mL | Oxiliplatin | 0.25 mg/mL |

**Linearity**

VIDAS® Free PSA rt kit linearity and dilution was evaluated according to CLSI EP06-A document. The concentrations are expressed in ng/mL.

- Linearity: A total of 4 human specimens were used to test serum dilutional linearity. Each of 4 individual human serum samples was quantitatively diluted with a low human male serum pool to obtain 7 dilutions at levels of 100% (neat sample), 75%, 50%, 25%, 10%, 5% and 0% (serum pool). Each of the dilutions was tested in quadruplicate on

a single instrument with a single reagent lot. The VIDAS Free PSA rt assay is linear over the entire measurement range.

- Dilution: A total of 6 human specimens were used to test dilutional linearity. Each of 6 individual subject samples was quantitatively diluted with bioMerieux TPSA assay sample diluent (ref.30428-01) to obtain 9 dilutions at levels of 100% (neat sample), 80%, 60%, 40%, 20%, 10%, 5%, 2% and 0% (sample diluent). The results for 3-4 replicates for each dilution for each of the 6 specimens were used in the analysis; the number of replicates used per specimen was dependant on the volume of the initial sample available for testing. Each of the dilutions was tested on a single instrument with a single reagent lot. The VIDAS Free PSA rt assay is linear over the entire measurement range when the VIDAS TPSA sample diluent is used.

## WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

## LITERATURE REFERENCES


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## INDEX OF SYMBOLS

| Symbol | Meaning |
|---|---|
| REF | GB : Catalogue number<br>US : Catalog number |
| IVD | In Vitro Diagnostic Medical Device |
|  | Manufacturer |
|  | Temperature limitation |
|  | Use by |
| LOT | Batch code |
|  | Consult Instructions for Use |
|  | Contains sufficient for <n> tests |

## WARRANTY

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